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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,695

04/14/2004

Levent Oner

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EXAMINER

MAHYERA, TRISTAN J

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/824,695	Applicant(s) ONER ET AL.	
	Examiner TRISTAN J. MAHYERA	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-10 are pending. Claims 1, 3-6, 8 and 10 have been amended. Claims 1-10 are examined on the merits.

Information Disclosure Statement

Receipt of the IDS filed 2/21/2008 and the fee paid under 1.17(p) is acknowledged and the documents considered.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(a-d), 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Specification

The objection to the specification is hereby **withdrawn** in light of the amendments.

Claim Objections

The objection to Claim 1 is hereby **withdrawn** in light of the amendments.

Claim Rejections - 35 USC § 112 1st Paragraph

The statute under this section can be found in a prior office action.

The rejection of Claims 4 and 6 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is hereby **withdrawn** in light of the amendments.

Claim 10 is **newly** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 10 was amended to "consists essentially of" from "comprises", which means that the scope of the claim may have changed to encompass subject matter that materially effects the invention, however, the specification gives no indication as to what materially affects the novel characteristics of the invention or what is a non-material limitation. Therefore, because of a lack of a clear indication of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." This is a new matter rejection.

Claim Rejections - 35 USC § 112 2nd Paragraph

The statute under this section can be found in a prior office action.

The rejection of Claims 3-6 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

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which applicant regards as the invention is hereby **withdrawn** in light of the amendments.

Claims 1-10 are **newly** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 and 10 have been amended to include alginic acid or sodium alginate “in an amount therapeutically effective to prevent esophageal reflux, heartburn and esophagitis in a patient taking alendronate...”. There is no explanation in the specification to clarify what is a therapeutically effective amount of alginic acid or sodium alginate. The only amount even shown is for sodium alginate at 300mg in the Example on page 5 of the specification, however, this is not limiting and does nothing to particularly point out what is a “therapeutically effective amount” to reduce the side effects of alendronate. Therefore, any amount of alginic acid or sodium alginate is deemed a therapeutically effective amount.

Claim Rejections - 35 USC § 103

The statute under this section can be found in the prior office action.

Claims 1-10 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over CLANCY et al. (WO 03/003999, see PTO-892) in view of PATEL et al. (US 6,248,363, see PTO-892). The body of this rejection can be found in a prior office action.

Response to Arguments

Applicant's arguments regarding a therapeutically effective amount of sodium alginate or alginic acid are moot in light of the new 112 rejection.

Applicants further argue they are taking advantage of the pH-dependent solubility of Eudragit E100 whereas CLANCY is only teaching enteric coatings, which are designed to degrade or dissolve in the intestinal tract and not the stomach. This is not found persuasive because PATEL clearly states that preferred polymers are acrylic, specifically the Eudragit E series which dissolve in the stomach. See e.g. col 43 lines 38-48. The reference further states that Eudragit E100 may be particularly suitable for taste masking applications or chemical protection. See e.g. col 42 lines 25 and 30-31. Applicants argue the purpose of the E100 is to coat the active so it will not dissolve in the mouth or esophagus, however, as shown in PATEL, E100 is known to dissolve not in the mouth or esophagus, but in the stomach thus its use as a taste masking coating or to protect the active chemical only reinforces the idea it is being used for its pH-dependent solubility so to prevent the active from reacting in the mouth, only in the stomach.

Applicants further state that CLANCY does not teach sachet forms of microparticle alendronate. The use of a sachet is taught in PATEL (see e.g. claims 29 and 52; col 41 line 46) and the use of coated microparticles is taught (see e.g. col 42 lines 5-6). Thus, the combination of CLANCY and PATEL teach coated alendronate microparticles in sachet form.

Conclusion

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRISTAN J. MAHYERA whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Friday 9am-7pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL P. WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615